



IFW

Docket No.: 0760-0346PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Hiroshi TAKAHASHI et al.

Application No.: 10/533,878

Confirmation No.: 9660

Filed: November 21, 2005

Art Unit: 1642

For: METHOD OF EXAMINING CANCER CELLS
AND REAGENT THEREFOR

Examiner: L. B. Goddard

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

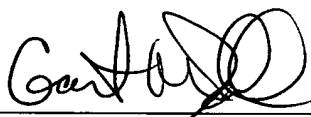
Enclosed herewith are copies of the documents that were cited in the International Search Report and listed on the Form PTO-SB08 filed with the Information Disclosure Statement on May 5, 2005.

The PTO is requested to make these documents of record in the file of the present application and to return the initialed Form PTO-SB08 to the undersigned.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fee required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: November 16, 2006

Respectfully submitted,

By  #43575
Gerald M. Murphy, Jr.
Registration No.: 28,977 for
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant

Attachments:

SUZUKI et al. Blood Vol. 90 (Suppl. 1 Part 1), page 513A, November 15, 1977



Docket No.: 0760-0346PUS1
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INFORMATION DISCLOSURE STATEMENT
(SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL
REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE
1.114 RCE APPLICATION)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

- ☒ a. Copies of cited U.S. patents and patent application publications are not included.
Copies of foreign patent documents and non-patent literature are included.

☐ b. Some or all of the documents listed on the PTO-SB08 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

☐ c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

☒ a. DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.

☐ b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

☒ c. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

☒ d. OTHER - The following additional information is provided for the Examiner's consideration. The references were cited in a Supplementary Search Report issued in a corresponding European application.

PARK SEUNGYOON ET AL. and TAKESHI ET AL., *Cancer Res.*, 1988, 48:6573-9, listed in the Supplementary Search Report, but not included in this Information Disclosure Statement, are already of record as it was cited in the Office Communication of July 28, 2006.

SUZUKI ET AL., *Blood*, 90(10 Suppl. 1 Part 1): 513A, also listed in the Supplementary Search Report, is not included in this IDS since it was previously submitted on May 5, 2005. However, a Letter is submitted herewith providing the Examiner a copy of the cited abstract.

IV. FEES (check one box)

☐ a. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

☐ b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required.

☐ c. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. *(This section is not to be used with RCE's.)*

☐ d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.

☐ e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.

☒ f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event

that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).

☐ g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

☐ No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.
or

☐ See the statement below. No fee is required.

V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check only one box)

The undersigned hereby states that:

☐ a. **Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or**

☐ b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☒ c. No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.

☐ d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI. PAYMENT OF FEES (check one box)


- ☐ The required fee is listed on the attached Fee Transmittal.
- ☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: November 16, 2006

Respectfully submitted,

By  #43525
Gerald M. Murphy, Jr. for
Registration No.: 28,977
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicants

Attachment(s):

- ☒ PTO-SB08
- ☒ Documents
- ☒ Foreign Search Report



PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031
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|---|---|----|---|--------------------------|------------------------|
| Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Complete if Known | |
| | | | | Application Number | 10/533,878-Conf. #9660 |
| | | | | Filing Date | November 21, 2005 |
| | | | | First Named Inventor | Hiroshi TAKAHASHI |
| | | | | Art Unit | 1642 |
| | | | | Examiner Name | L. B. Goddard |
| | | | | Attorney Docket Number | 0760-0346PUS1 |
| Sheet | 1 | of | 2 | | |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | AA* | US-6,008,002 | 12-28-1999 | Bodey | |
| | AB* | US-20010000751-A1 | 05-03-2001 | Schmitz et al. | |
| | AC* | US-20020009759-A1 | 01-24-2002 | Terstappen et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | |
|--------------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | BA | WO-95/24648-A1 | 09-14-1995 | FODSTAD et al. | |
| | BB | WO-93/06117-A1 | 04-01-1993 | The General Hosp. Corp. | |
| | BC | WO-01/19956-A1 | 03-22-2001 | BANDER | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|--|----------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | CA | J E HARDINGHAM ET AL, "Immunobead-PCR: A Technique for the Detection of Circulating Tumor Cells Using Immunomagnetic Beads and the Polymerase Chain Reaction", Cancer Research, American Association For Cancer Research, August 1, 1993, pages 3455-3458, Vol. 53 | |
| | CB | BRANDT B ET AL, "Isolation of Prostate-derived Single Cells and Cell Clusters from Human Peripheral Blood", Cancer Research, American Association for Cancer Research, October 15, 1996, pages 4556-4561, Vol. 15 No. 20 | |
| | CC | BEROIS N ET AL, "Detection of Rare Human Breast Cancer Cells. Comparison of an Immunomagnetic Separation Method with Immunocytochemistry and RT-PCR", Anticancer Research, Helenic Anticancer Institute, pages 2639-2646, Vol.17 | |
| | CD | LUKE ET AL, "Detection of Breast Cancer Cells in Blood Using Immunomagnetic Bead Selection and Reverse Transcription-Polymerase Chain Reaction", Molecular Diagnosis, September 1998, pages 149-155, Vol. 3 No. 3 | |
| | CE | SAKAGUCHI M ET AL, "Development of a sensitive, specific reverse transcriptase polymerase chain reaction -based assay for epithelial tumour cells in effusions", February 1999, pages 416-422, Vol. 79 No.3/4 | |
| | CF | TAKAHASHI H ET AL, "Radioimmunolocalization of Hepatic and Pulmonary Metastasis of Human Colon Adenocarcinoma", Gastroenterology, Saunders, May 1989, pages 1317-1329, Vol. 96 No.5 | |
| | CG | SUZUKI S ET AL, "Human lymphocytes activated by chimeric SF-25 monoclonal antibody induce apoptosis of HTLV-1 infected T-cell lines resistant against anti-Fas TNFalpha and IFNgamma", Blood, Vol. 92, No. 10, Suppl.1 Part 1-2, November 15, 1998, pages 248A | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

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|--|---|----|---|--------------------------|------------------------|
| Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | 10/533,878-Conf. #9660 |
| | | | | Filing Date | November 21, 2005 |
| | | | | First Named Inventor | Hiroshi TAKAHASHI |
| | | | | Art Unit | 1642 |
| | | | | Examiner Name | L. B. Goddard |
| Sheet | 2 | of | 2 | Attorney Docket Number | 0760-0346PUS1 |

| | | | |
|--|----|--|--|
| | CH | SUZUKI S ET AL, "Peripheral blood lymphocytes from patients with adult T-cell leukemia in remission induce apoptosis to HTLV-1 infected T-cell line by activation with chimeric SF-25 monoclonal antibody" November 15, 1999, page 98a, Blood Vol. 94, No. 10, Suppl. 1 Part 1 | |
| | CI | SUZUKI S ET AL, "Human lymphocytes activated by chimeric kSF-25 monoclonal antibody induce apoptosis of HTLV-1 infected T-cell line" JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROMES AND HUMAN RETROVIROLOGY, Vol. 20, No. 4, April 4, 1999, page A61 | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|